MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilitie distributors and manufact for MANDATORY reportir

Form Approved by FDA on 01/23/97

Individual Safety Report

3136028-1-00-01

FDA Use Only

Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
19981284[redacted]	63	○ Female	lbs
In confidence	or ----------	● Male	or
	Date of birth:		kgs

B. Adverse event or product problem

1. ☒ Adverse Event and/or ☐ Product problem (e.g., defects/malfunction:

2. Outcomes attributed to adverse event (check all that apply)

☒ death _____ (mo/day/yr)
☐ life-threatening
☐ hospitalization - initial or prolonge
☐ disability
☐ congenital anomaly
☐ required intervention to prever permanent impairment/damage
☐ other:

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
Aug-10-98	Sep-23-98

5. Describe event or problem

This is an initial report classified as serious and unexpected based on information received by Covance 15 September 1998.

On 06 May 1998 a 63-year-old male patient from the USA ɜan treatment with nilutamide, 150 mg/QD, for his prostate .ıcer. The patient's significant medical history includes a radical prostectomy in 1991 and radiation to the local area in 1994. Concomitant medications include leuprolide acetate (injections 6 May 1998 and July 1998), paracetamol, anti-inflammatories, and sildenafil citrate.

The patient experienced hepatic failure on 10 August 1998 and died approximately one week prior to 11

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Radical prostectomy - 1991
Radiation local area - 1994

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Nilutamide, 50 mg, Hoechst Marion Roussel
#2 Tylenol

2. Dose, frequency & route used	3. Therapy dates (if unknown,give duration) from/to (or best estimate)
#1 150mg/QD PO	#1 May-06-1998 unknown
#2 2 Tabs/QID PO	#2 unknown

4. Diagnosis for use (indication)
#1 unknown
#2 unknown

5. Event abated after use stopped or dose reduced
#1 ○ yes ○ no ● n/a
#2 ○ yes ○ no ● n/a

6. Lot # (if known)	7. Exp. date (if known)
#1 unknown	#1
#2 unknown	#2

8. Event reappeared after reintroduction
#1 ○ yes ○ no ● n/a
#2 ○ yes ○ no ● n/a

9. NDC # - for product problems only (if known)
0088-1110-35

10. Concomitant medical products and therapy dates (exclude treatment of event)
leuprolide acetate May-06-98
paracetamol
anti-inflammatories

G. All manufacturers

1. Contact office - name/address (& mfring site for device)
Covance
210 Carnegie Center
Princeton NJ 08540
U.S.A.

2. Phone number
609-452-8550

3. Report source (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consumer
☒ health professional
☐ user facility
☒ company representative
☐ distributor
☐ other

4. Date received by manufacture (mo/day/yr)
Sep-10-98

5. (A)NDA #20-169
IND #
PLA #
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
☐ 5-day ☒ 15-day
☐ 10-day ☐ periodic
☒ Initial ☐ follow-up 1

8. Adverse event term(s)
Liver Failure

9. Mfr. report number
98-PR1012

E. Initial reporter

1. Name, address & phone #
[redacted] United States
[redacted] 1998

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
● Yes ○ No	Urologist	○ Yes ○ No ● unk

FDA Form 3500A Facsimile
Covance

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user distributors and m: for MANDATORY

Form Approved by FDA on 01/29/97

Individual Safety Report

3136026-1-00-02

FDA use only

Patient information

1. Patient identifier: 19981284[redacted] In confidence

2. Age at time of event: 63 or ____ Date of birth:

3. Sex: ○ Female ● Male

4. Weight: lbs or kgs

B. Adverse event or product problem

1. ☐ Adverse Event and/or ☐ Product problem (e.g., defects/malfunction:

2. Outcomes attributed to adverse event (check all that apply)

☐ death ____ (mo/day/yr)
☐ life-threatening
☐ hospitalization - initial or prolonge
☐ disability
☐ congenital anomaly
☐ required intervention to prever permanent impairment/damage
☐ other: ____

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

September 1998; the actual date of death is unknown at this time. The physician states that the hepatologist felt that the event was Nilandron-related. The physician also mentioned the patient had been taking 2 Tylenol (paracetamol) every 4 hours for a long time, and Tylenol is a contributing factor.

'ditional information has been requested.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

2. Dose, frequency & route used

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

4. Diagnosis for use (indication)

5. Event abated after use stopped or dose reduced
○ yes ○ no ○ n/a
○ yes ○ no ○ n/a

6. Lot # (if known)

7. Exp. date (if known)

8. Event reappeared after reintroduction
○ yes ○ no ○ n/a
○ yes ○ no ○ n/a

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)
sildenafil citrate

G. All manufacturers

1. Contact office - name/address (& mfring site for device)

2. Phone number

3. Report source (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consumer
☐ health professional
☐ user facility
☐ company representative
☐ distributor
☐ other

4. Date received by manufacturer (mo/day/yr)

5. (A)NDA #
IND #
PLA #
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
☐ 5-day ☐ 15-day
☐ 10-day ☐ periodic
☐ Initial ☐ follow-up #

8. Adverse event term(s)

9. Mfr. report number
98-PR1012

E. Initial reporter

1. Name, address & phone #

1998

2. Health professional? ○ Yes ○ No

3. Occupation

4. Initial reporter also sent report to FDA
○ Yes ○ No ○ unk

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